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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/716,329

11/18/2003

Fred H. Burbank

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EXAMINER

TYSON, MELANIE RUANO

ART UNIT

PAPER NUMBER

3773

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/716,329	<b>Applicant(s)</b> BURBANK ET AL.	
	<b>Examiner</b> Melanie Tyson	<b>Art Unit</b> 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 10-13,40-43,45,46 and 50-64 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-13,40-43,45,46 and 50-64 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

This action is in response to Applicant's amendment received on 03 December 2007.

#### ***Response to Arguments***

Applicant's arguments with respect to claims 10-13, 40-43, 45, 46, and 50-58 have been considered but are moot in view of the new ground(s) of rejection.

#### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 46 and 50-64 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. At the time the application was filed, the applicant failed to disclose specifically that the lumen of the collar is non-threaded. Applicant simply disclosed a collar having a lumen which allows slidable motion over a threaded outer portion of the guide rail, in which a threaded lumen would allow a slidable motion over a threaded portion of the guide rail. Therefore, the limitations "a movable collar including a non-threaded internal lumen" (claim 46) and "collar having a non-threaded internal lumen" (claims 54 and 60) are considered new matter. With further respect to claims 59 and 60, applicant discloses a driving member disposed at

the *proximal end* of the guide rail. Therefore, the limitation “a driving member disposed *between* the collar and the *proximal end* of the guide rail” is considered new matter.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 54 and 59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite a collar adapted to slide freely over “a threaded portion of the guide rail” and the driving member having internal threads adapted to engage the “threaded section” of the guide rail. Applicant has not positively recited a threaded portion on the guide rail, thus making the scope of the claims unclear. For examination purposes, the claims have been interpreted as requiring simply an elongated guide rail, a movable collar having a non-threaded internal lumen, and a driving member. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 40-43, 46, 54, and 59 are rejected under 35 U.S.C. 102(b) as being anticipated by Hasson (5,562,680). Hasson discloses an intravaginal tenaculum-like device (see entire document) comprising an elongated guide rail (12), a collar (46) including a non-threaded internal lumen, a medical instrument movably mounted to the

Art Unit: 3773

guide rail distal to the movable collar (portions 18 and 20), a tissue grasping assembly comprising a first elongated member secured to the guide rail (end portion of 12) and a second elongated member (32) pivotally connected to the first elongated member (at pivot pin 52), and a securing element (28) having a sharp point. The collar of Hasson is held together on the guide rail by screws, which may be loosened such that the collar may selectively be placed along the guide rail. Therefore, the collar disclosed by Hasson is movable as claimed and is adapted to slide freely over the outer surface of the guide rail as claimed. Hasson further discloses a driving member (100) coupled with the guide rail proximal to the collar for selectively advancing the collar toward the distal end of the guide rail, in that a pulling back motion would advance the collar with loosened screws toward the distal end of the guide rail. Regarding claim 43, the guide rail portion contains no obstructing protrusions, thus is configured to receive a slidable coupling element as claimed.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

Art Unit: 3773

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 10-13, 50-53, and 55-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hasson in view of Mohajer (5,464,409). Hasson discloses a device as described above, however, fails to disclose the tip of the guide rail comprises expandable bifurcated portions. Mohajer discloses an intravaginal tenaculum-like device (see entire document). Mohajer teaches a uterine manipulator (10) comprising a guide rail (18), wherein the distal tip is expandable and split into bifurcated portions (for example, see column 5, lines 49-56) having different radii of curvature. It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the distal tip of Hasson as taught by Mohajer in order to provide a device that can hold itself in place during the procedure by engaging portions of the uterus, uterine cavity, and cervix (column 4, lines 48-53 and column 5, lines 45-49), thus facilitating the procedure.

8. Claims 45 and 60-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hasson in view of Topel et al. (5,488,958). Hasson discloses an intravaginal tenaculum-like device (see entire document) comprising an elongated guide rail (12), a collar (46) including a non-threaded internal lumen, a medical instrument comprising sleeves (68) movably mounted to the guide rail distal to the movable collar (portions 18 and 20), a tissue grasping assembly comprising a first elongated member secured to the guide rail (end portion of 12) and a second elongated member (32) pivotally connected to the first elongated member (at pivot pin 52), and a securing element (28)

having a sharp point. The collar of Hasson is held together on the guide rail by screws, which may be loosened such that the collar may selectively be placed along the guide rail. Therefore, the collar disclosed by Hasson is movable and rotatable as claimed.

Hasson further discloses a driving member (100) coupled with the guide rail proximal to the collar for urging the collar toward the distal end of the guide rail, in that a pulling back motion would urge the collar with loosened screws toward the distal end of the guide rail. Hasson fails to disclose the guide rail includes a threaded section and the driving member includes internal threads for engaging the threaded section of the guide rail.

Topel discloses a medical device (see entire document) comprising a driving member (18) and a collar (11). Topel teaches technique in which a guide rail includes a threaded section and the driving member includes internal threads, such that rotation of the driving member around a longitudinal axis of the guide rail provides longitudinal movement of the collar (for example, see Figures 1-3). It is well within the general knowledge of one having ordinary skill in the art to apply a known technique to a known device ready for improvement to yield predictable results. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate threads in the device of Hasson as taught by Topel. Doing so would make it easier for a user to position the collar, in turn the medical instrument, on the guide rail, thus providing an apparatus that easily accommodates virtually all patients.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571)272-9062. The examiner can normally be reached on Monday through Friday 9-5:30 (max flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for



Art Unit: 3773

published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson /M. T./  
Examiner, Art Unit 3773  
February 25, 2008

/(Jackie) Tan-Uyen T. Ho/  
Supervisory Patent Examiner, Art Unit 3773